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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/680,465 10/06/00 JAPUNTICH

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EXAMINER

QM32/0717

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ART UNIT

PAPER NUMBER

3761

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07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
09/680,465

Applicant(s)  
DANIEL A. JAPUNTICH ET AL.

Examiner  
AARON J. LEWIS

Art Unit  
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Oct 6, 2000

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 33-65 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 33-65 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Objections***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 58-66 been renumbered 57-65.

### ***Double Patenting***

2. Claims 33-65 of this application conflict with claims 34-77 of Application No. 08/240,877; 34-77 of 09/440,619; 33-65 of 09/678,580; 33-62 of 09/678,579; 33-61 of 09/678,488; 33-56 of 09/677,637; 33-64 of 09/677,636. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

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***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the valve cover having a surface that holds the flexible flap against the flap-retaining surface on the valve seat and the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 34, 58 and 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 58, "...the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping." is not disclosed in the specification.

In claims 34 and 64, "...the valve cover has a surface that holds the flexible flap against the flap-retaining surface on the valve seat." is not disclosed in the specification.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 33,35-46,48-57,59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al.('516).

As to claim 33, Simpson et al. disclose a filtering (page 1, lines 108-113) face mask (1,2) that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig.1); and an exhalation valve (12) that is attached to the mask body, the exhalation valve comprising: a valve seat that comprises: a seal surface (page 2, lines 37-50 and #19) and an orifice (16) that is circumscribed by the seal surface; cross members (surfaces between orifices 16) that extend across the orifice to create a plurality of openings within the orifice, the cross members being slightly recessed beneath the seal surface; and a single flexible flap (15) that has a fixed portion (page 2, lines 46-50) and a free portion and first and second opposing ends (page 2, lines 42-50), the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, wherein the flexible flap is positioned on the valve seat such that the flap is pressed

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towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice (page 2, lines 41-50).

As to claims 35-36, the valves (figs.2 and 3) of Simpson et al. (page 2, lines 37-65) are disclosed as being made of plastic and/or rubber material. It would have been obvious to fabricate the valves by any well known technique which is known to be employed in the fabrication of plastics and rubber including the technique of injection molding.

As to claim 37, Simpson et al. disclose the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. are illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, the flap (15) of Simpson et al. being made from plastic is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface."

As to claim 38, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claims 39 and 42, the flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such

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a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claims 40 and 41, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one ordinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 43-46,48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 51, the flange against which the valve flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

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As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. fig. 1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body of mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig. 1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claim 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 57, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig. 1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig. 2) in cantilever fashion.

As to claim 59, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface surrounds the orifice.



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8. Claims 34,58 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. as applied to claims 33,35-46,48-57,59 above, and further in view of French patent (1,209,475).

The difference between Simpson et al. and claim 34 is a valve cover that has a surface that holds the flexible flap against a flap retaining surface on the valve seat.

French patent ('475) teaches a valve cover (#2 of figs.3 and 4) that has a surface that holds (15,35) the flexible flap against a surface on the valve seat.

It would have been obvious to modify the valve of Simpson et al. to employ a cover because it would have provided protection for the exhalation valve and because it would have provided a means for accessing the valve for cleaning and/or replacement as taught by as taught by French patent ('475).

As to claim 58, French patent ('475) teaches a valve cover (#2 of figs.3 and 4), the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping.

As to claim 64, the valve cover of French patent ('475) has a surface that holds the flexible flap against a flap-retaining surface (15) on the valve seat (figs.3 and 4).

9. Claims 60-63,65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of French patent ('475) as applied to claims 34,58 and 64 above, and further in view of Courtney ('134).

As to claim 60, the valve cover of French patent ('475) is illustrated in figs.3 and 4 to have an opening that is disposed directly in the path of fluid flow when a free portion of the flexible flap

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(14) is lifted from the seal surface during an exhalation; a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end.

The difference between Simpson et al. as further modified by French patent ('475) and claim 60 is cross members that are disposed within the opening of the valve cover.

Courtney, in a filtering face mask, teaches a valve cover (3) that is disposed over the valve seat and that comprises: an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation; a fluid impermeable ceiling (the material of cross members (19) is fluid impermeable) that increases in height in the direction of the flexible flap from the first end to the second end; and cross members (19) that are disposed within the opening of the valve cover for the purpose of protecting the valve and valve opening (col.2, lines 8-11).

It would have been obvious to further modify the valve of Simpson et al. to employ cross members across the opening of the cover because it would have provided additional protection for the exhalation valve as taught by Courtney.

As to claim 61, the valve cover of French patent ('475) is illustrated in figs.3 and 4 as being approximately parallel to the path traced by the second end of the flexible flap (14) during its opening and closing.

As to claim 62, Simpson et al. as further modified by French patent ('475) teach a cover which is fully capable performing the recited function of directing exhaled air downwards when the mask is worn by a person.

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As to claim 63, the cover of French patent (figs.3 and 4) illustrates fluid-impermeable sidewalls.

As to claim 65, the opening in the cover of French patent ('475) is at least the size of the orifice in the valve seat as illustrated in figs.3 and 4.

10. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. as applied to claims 33,35-46,48-57,59 above, and further in view of McKim ('168).

The difference between Simpson et al. as modified by Courtney and claim 47 is one free portion of the flexible flap having a curved profile.

McKim ('618) teaches a valve flap having a fixed portion (14a) and a free portion (opposite the fixed portion as illustrated in figs.1 and 3), the one free portion of the flexible flap having a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface. McKim teaches a curved seal surface and curved flexible flap for the purpose of seating quickly, effectively and without float or bounce after each opening (col.1, lines 64-72).

It would have been obvious to modify the flexible valve flap and seat of Simpson et al.(fig.2) to be curved because it would have provided quick seating, in an effective manner and without float or bounce after each opening as taught by McKim.

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Additionally, the one free portion of the flexible flap of Simpson et al. as further modified by McKim (figs. 1,5) has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

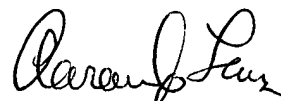
***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant filtering face masks including exhalation valves.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

July 16, 2001

  
Aaron J. Lewis  
Primary Examiner

**Attachment for PTO-948 (Rev. 03/01, or earlier)**

**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.